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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,111

10/12/2006

Stefan Barth

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7590

08/17/2010

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT

PAPER NUMBER

1652

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,111	<b>Applicant(s)</b> BARTH ET AL.	
	<b>Examiner</b> MD. YOUNUS MEAH	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/7/10.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19,21,25,26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19,21,25,26 and 29 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' election of group 1 (claims 1-15, 21, 25 and 26) submitted on 6/7/10 in response to the restriction requirement of 5/7/2010 is acknowledged. Upon further consideration, the previous restriction requirement of 5/7/2010 is hereby withdrawn. A new restriction requirement follows.

Claims 1-19, 21, 25-26, and 29 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions are distinct, each from the other because of the following reasons:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups A<sub>n</sub>, claims 2-15, 21, 25-26, and 29, drawn to a single combination of fusion proteins comprising a component A selected from the list of components A recited in the claims (e.g., claims 2, 3, etc), and component B, selected from the list of components B recited in the claims (e.g., claim 6, 7, 8, 9, etc.). A<sub>1</sub>, A<sub>2</sub>, A<sub>3</sub>, etc. each represent a single combination of components A and B. N represents the total number of possible combinations of A and B one could make of all the recited compounds A and B, which

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has not been calculated in view of the enormous number of possible combinations encompassed by the claims.

Groups B<sub>1-3</sub>, claims 16-18 drawn to a nucleic acid encoding amino acid sequence of SEQ ID NO: 2, 4 and 6, and host cell expressing said nucleic acid, wherein B<sub>1</sub> is referred to a nucleic acid encoding amino acid sequence of SEQ ID NO: 2, and host cell expressing said nucleic acid; B<sub>2</sub> is referred to a nucleic acid encoding amino acid sequence of SEQ ID NO: 4, and host cell expressing said nucleic acid; and B<sub>3</sub> is referred to a nucleic acid encoding amino acid sequence of SEQ ID NO: 6 and host cell expressing said nucleic acid.

Groups C<sub>1-3</sub>, claim 19 drawn to a method of effecting the growth of cells comprising nucleic acid encoding amino acid sequence of SEQ ID NO: 2, 4 and 6, wherein C<sub>1</sub> is referred to the method of effecting the growth of cells expressing the nucleic acid encoding amino acid sequence of SEQ ID NO: 2, and host cell expressing said nucleic acid, C<sub>2</sub> is referred to the method of effecting the growth of cells expressing the nucleic acid encoding amino acid sequence of SEQ ID NO: 4, B<sub>3</sub> is referred to the method of effecting the growth of cells expressing the nucleic acid encoding amino acid sequence of SEQ ID NO: 6.

The inventions listed in claims 1-19, 21, 25-26, 29 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature shared by all those enormous number of groups is a fusion protein comprising binding domain molecule and protein kinase.

However; fusion protein comprising binding domain molecule and protein kinase does not constitute a “special technical feature” as defined by the PCT Rule 13.2, because it does not claim a feature which defines a contribution over the prior art as fusion protein comprising binding domain molecule and protein kinase is taught by Littman et al (US PAT 5670324).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Each kinase domain, component A, of the fusion proteins encompassed by the instant claims is a protein having a different structure and a different substrate. Similarly, each component B, a specific binding domain, encompassed by the instant claims is a structurally and functionally different molecule. N number of kinase domains in combination with N number of binding domains will produce  $N^2$  (such as  $10 \times 10 = 100$ ) patentably distinct fusion complexes having different structures. Therefore, each combination of fusion proteins comprising a component A and comprising a component B is patentably distinct and not obvious over the others. As such each fusion protein is an independent invention. In view of the enormous number of independent inventions encompassed the examiner has not attempted to exhaustively list each independent invention herein. Applicants are required to identify a specific fusion protein for examination by electing a specific kinase and a specific binding domain. Applicants are further required to identify which claims encompass the elected invention. For example,

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applicant may elect a fusion protein (immunokinase) which is a fusion of death-associated protein kinase, DAPKk with immunoglobulin variable region and which comprises SEQ ID NO: 2 ( in claim 15) and include other claims which are related to the function of the protein of SEQ ID NO: 2.

Claim 1 link(s) inventions  $A_n$ . The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The Examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah  
Examiner, Art Unit 1652

/Delia M. Ramirez/  
Primary Examiner, Art Unit 1652